

Defibrillator Failures

As many as 1,000 cardiac arrests occur every day in the United States. In most of these cases, the patient's heart is in ventricular fibrillation; that is, the coordinated conduction of the electrical stimuli that cause the ventricles to contract is disrupted, and the heart stops pumping blood to the rest of the body. Electrical defibrillation is currently the most effective means of stopping fibrillation. But when a defibrillator fails and resuscitation is delayed, the consequences can be fatal. As the resuscitation team locates a backup unit, the patient's condition deteriorates, and subsequent defibrillation attempts are less likely to succeed. Obviously, there is little margin for error when operating life-support devices. Unfortunately, defibrillators fail all too frequently, and the causes of a high percentage of these failures are errors in use or in defibrillator care and maintenance.

This article reviews the causes of defibrillator failures and discusses actions to help ensure the safe and reliable performance of these life-support devices.

Findings of the Defibrillator Working Group

To investigate possible causes of defibrillator failures* and to recommend solutions, the Defibrillator Working Group** of the Food and Drug Administration (FDA) reviewed more than 1,300 reports of defibrillator problems, including data from ECRI's International Problem Reporting System and the the Defibrillator Working Group includes clinicians, emergency medical services personnel, an ECRI scientist, and manufacturers' representatives. The group's objectives were to enlighten defibrillator users about the potential for errors in operator performance and periodic maintenance and to recommend improvements in training, maintenance, and defibrillator design. FDA's Medical Device Reporting (MDR)

* This article addresses problems encountered with external defibrillators and does not discuss the implanted devices. It also focuses on manual units, rather than automatic or semiautomatic units, although Appendix C presents recommendations for automatic units.

** From 1984 through 1988, 495 defibrillator problems were reported to the MDR system.

system. The group concluded that more defibrillator failures occur because of errors in use or in device care and maintenance than as a result of component malfunctions.

User-related problems accounted for 30% of the total.¹ And, while some reports involved component failures (e.g., overheated or depleted batteries, faulty discharge switches and paddle retention assemblies, loose cable connections), many of these problems may actually have been related to errors in use or maintenance. For example, a common problem was failure of the device to deliver a shock when the controls were pressed. In some cases, the apparent device failure occurred because users:

- held the device in a charge state so long that the device internally "dumped" the charge;
- changed the selected energy level after charging, causing the unit to internally discharge; and/or
- attempted emergency defibrillation with the unit in the synchronous mode (a mode used to treat arrhythmias other than ventricular fibrillation that requires some sort of coordinated cardiac activity to trigger the defibrillator discharge).¹

During the same four-year period, ECRI, through its Problem Reporting System, received 156 reports of problems with external, manual defibrillators. A number of these problems were discussed in *Health Devices* hazard reports. The reports fell into three categories.

Operator Errors in Maintenance. Among the problems that resulted from improper maintenance were corroded internal paddles from inappropriate sterilization, deteriorating and flaking insulation on internal paddles,

HRC TOOLS FOR THIS TOPIC

The following tools and resources on this topic are available in your *HRC System*. Refer to this article, your *HRC Index*, the online system, and other *HRC* resources for help.

- Checklists
- Action Recommendations

Disposable Defibrillator Pads and Electrodes

Delivering sufficient current to the heart depends in part on the conductive medium that is placed against the patient's chest. The type of medium can affect both the amount of current that is delivered through it and the time it takes to deliver it.

Traditionally, user-held paddles — which are metal contacts with plastic handles — have been used with a conductive gel, cream, or paste. However, conductive gel has been associated with certain risks for the patient and operator: gel smearing can increase the risk of skin burns at the electrode site and cause a loss of current as it flows across, instead of into, the chest; gel on the patient's chest can hamper CPR; gelled paddles are difficult to hold firmly in position; and operators may be shocked during defibrillation through contact with excess gel.

Disposable paddle pads and disposable electrodes are applied differently: pads are placed on the patient as the conductive medium against which hand-held paddles are pressed; electrodes adhere to the chest and allow hands-off defibrillation. Both eliminate problems associated with gel smearing, but they can be damaged under adverse storage conditions.

While disposable pads offer certain advantages over gel in any hospital or prehospital setting, disposable electrodes may be preferable to pads or gel, depending on the application. Using disposable electrodes obviously changes the routine defibrillation procedure, possibly causing delays if clinical users are unfamiliar with the use of electrodes and their adapters. This may

pose special training problems in hospitals with high staff turnover. Hospitalwide standardization is difficult because electrode manufacturers offer different adapters for different brands of defibrillators. Also, with hands-off electrode defibrillation, staff members no longer bring the paddles down onto the patient's chest to deliver a shock. More care is needed to alert others when a shock is being delivered.

Disposable electrodes are probably best suited for use in the cardiac catheterization and electrophysiology laboratories because electrodes can be applied in advance, and sterile drapes used in many procedures need not be disturbed. As a result, patients are defibrillated sooner.

In cramped areas or in moving ambulances, electrodes are probably easier and quicker to use than defibrillator paddles and may provide a cleaner ECG for a fast diagnosis. However, limited storage space in ambulances may complicate the storage of electrodes in the proper orientation, and paddles may not be available as a backup if electrodes are found to be unusable. Also, if the electrodes used in the ambulance are not compatible with the hospital's system, time could be lost while switching defibrillator cables; if they are compatible, however, cables can be switched easily for a rapid and efficient patient transfer.

(For a thorough discussion of the use and selection of defibrillator pads and electrodes and for comparative ratings of evaluated products, see *Health Devices* 1990 Feb; 19:33-56.)

device damage caused by improper testing, spilled fluids, dirty paddles, and loose cable connectors. In one case, a unit failed to charge during a defibrillation attempt because the AC line power switch, a switch separate from the front-panel ON switch and out of normal sight, had inadvertently been turned OFF, disconnecting the unit and its internal battery charger from line power.² In another case, battery depletion occurred following incorrect placement of the defibrillator chassis into its charger base. Other failures were attributed to inconsistent operational checks, poor preventive maintenance, and poor or delayed reporting of operational problems to clinical engineering.

Operator Errors in Clinical Use. Reported problems in this category included inadvertent activation of the SYNC button when paddle cables were pulled across it. The SYNC button activates the synchronous mode, a

feature present on many defibrillators and defibrillator/monitors. As noted previously, the synchronous mode requires some coordinated cardiac activity to trigger the defibrillator discharge. In the absence of that activity, such as when the monitor detects fine ventricular fibrillation or asystole (common arrhythmias in cardiac arrest), the defibrillator will not discharge.³

Another problem report involved a fire that occurred when sparks arced in an oxygen-enriched atmosphere following a lengthy, unsuccessful resuscitation attempt on a cardiac arrest patient. A review of this incident by hospital personnel suggested that the fire was ignited by an arc at one of the external defibrillator paddles. The arc, which may have been caused by inadequate pressure on the paddles, may have shunted to an ECG lead draped over the patient's shoulder and ignited a small area in the bed sheet. The ventilator

Internal Paddles

There is little margin for error when operating life-support devices, such as defibrillators. There have been a number of problems reported with internal paddles, including corrosion of the paddle surfaces, corrosion of the paddle shafts and jacks inside the handles, switch malfunctions, and cable discontinuity (breaks). Therefore, special care should be taken with these paddles to prevent a failure that might jeopardize the defibrillation attempt.

Internal paddles should be routinely inspected for signs of corrosion or failure during the cleaning and sterilization procedure that follows each use. Clean and sterilize internal paddle sets according to the manufacturer's instructions. Some manufacturers do not recommend immersing the paddles in cleaning solutions but prefer brushing or wiping off contaminants with an approved solvent. When in doubt about a solvent or cleaning technique, contact the manufacturer, or consult the product literature for recommended procedures and products.

Paddle sets should be sterilized between uses. Disinfection with Cidex is not a suitable substitute. Most manufacturers recommend ethylene oxide (EtO) sterilization and do not allow their paddles to be steam sterilized due to problems with corrosion.

Those paddle sets that allow the paddle plates to be removed from the handles often have depressed jack connections that can trap fluids. During cleaning, position the handles so that the fluid drains out.

Routine defibrillator preventive maintenance and testing (usually performed by clinical engineering) should include testing internal defibrillator paddles. Each paddle set should be checked for corrosion and electrical continuity. The paddle connector pins should also be examined for proper alignment and any signs of arching. Internal paddle performance should be checked at a low energy level (up to 50 J), using a defibrillator analyzer.

Not all paddles can be tested at one time. Sterile paddles must be available for those operating rooms

that regularly use them. Internal paddles rarely come with any kind of identification number, making it difficult to keep track of those sets that have been tested and those that have not. It may be necessary to tag each set for easy identification and tracking.

Internal paddles go through a number of sterilizations, placing wear and tear on the paddle surfaces, connectors, and possibly the switches. They should be replaced after a specific number of cycles. Some manufacturers recommend 100 cycles; others recommend 200 cycles or after two years. The manufacturer should be able to supply you with suggested life cycles for its paddles.

However, this kind of replacement can only be carried out effectively if your internal paddle sets are marked with some sort of identification for tracking.

A Final Note

The likelihood of operator error can often be decreased through modifications, in either equipment or use, provided the manufacturers are aware of the problems and how frequently they occur. For example, after learning of the problems of inadvertent shutoff of the AC line power switch on its defibrillator, one manufacturer developed an adhesive-backed plastic cap contoured to keep the switch in the ON position.⁷

Unfortunately, clinical and bioengineering personnel are sometimes reluctant to report defibrillator/monitor problems to ECRI and the manufacturer because of liability concerns; should the hospital not take action when an operator misuses a defibrillator and that error recurs, the hospital's liability may be greater. Clinical users should report any problems to clinical engineering or other service personnel, who can then alert the hospital risk manager, the manufacturer, and ECRI. The sooner the problem is reported, the quicker the manufacturer or ECRI can recommend modifications that would reduce the risk of patient injury. Indeed, users are *required* to report certain equipment-related problems to the manufacturer and/or FDA under the Safe Medical Devices Act of 1990.⁸

tubing had been disconnected from the patient's endotracheal tube before the first defibrillation attempt; the tubing was left on the bed near the patient's chest and an ECG lead. During resuscitation, the ventilator continued to deliver 100% oxygen through the tubing, creating an

unsuspected oxygen-enriched atmosphere. (Resuscitation in this case was unsuccessful, and the patient had been declared dead moments before the fire was observed; no other patients or personnel were injured as a result of this incident.)⁴

Defibrillators and Human Factors Issues

In late 1989, the first international symposium on Human Factors in Medical Devices (sponsored by ECRI, FDA, CITECH, and the Health Industry Manufacturers Association (HIMA) brought together medical device designers, manufacturers, users, regulators, and evaluators to develop concrete suggestions for reducing the risk of user error with medical devices. Some symposium participants addressed the human factors problems of emergency care devices, particularly manual defibrillators. The group identified a number of problems and possible solutions, several of which are reviewed here.*

Operating Mode Not Obvious. Defibrillators are becoming more complex with such built-in features as synchronized cardioversion, ECG monitoring, and pacing capabilities, as well as self-diagnostic/service modes. As the number of operating modes increases, so does the likelihood of user errors. As noted previously, one problem reported to the MDR system involved attempted defibrillation in the SYNC mode. A similar problem can occur with defibrillators that have service modes that allow the internal circuitry to be checked without requiring that the case be opened.

* Copies of the complete *First Symposium on Human Factors in Medical Devices*, are available from ECRI.

These units could be returned to clinicians with the nonstandard mode still engaged. (ECRI has received a problem report related to this service mode.)

In an effort to prevent such problems, many defibrillators now automatically revert to the defibrillation mode after delivering a synchronized shock or after testing in the service mode; however, a lack of standardization can lead to confusion and error. Defibrillators should incorporate an explicit visual display stating the engaged mode of operation. In the meantime, users must be familiar with all operating modes and recognize the potential for confusion and error. This is particularly important because relatively few healthcare professionals use a defibrillator/monitor frequently.

Improper Maintenance. Improper maintenance and/or inadequate device checks lead to device failures in critical situations. Defibrillators and their accessories in both the hospital and prehospital setting should be visually checked at least daily by the intended user and after each use; these checks should be documented in writing. Deficiencies should be reported to the personnel responsible for the equipment repair and maintenance.

Automatic Disarm Feature. Most defibrillators have an automatic disarm feature that protects a

In some cases, problems resulted because users simply had inadequate knowledge of proper device operation. In one hospital, for example, a nursing assistant was injured when she held "quick-look" paddles to her own chest to check the defibrillator's ECG monitor, then accidentally charged and discharged the defibrillator. The hospital stated that other inadvertent discharges occurred when a manufacturer's technicians placed paddles on themselves to check the monitor, rather than connecting the patient lead cable to an ECG simulator.⁵

Device Component Failures. Problems in this category were similar to component failures uncovered in the MDR data — overheated or failed batteries, faulty discharge switches and paddle retention assemblies, and cable connector problems.

The CDRH Defibrillator-Use Survey

The Defibrillator Working Group also reviewed data collected in the FDA's Center for Devices and Radiological Health (CDRH) five-state survey of 212 healthcare facilities and prehospital EMS units.¹ The survey,

intended to examine defibrillator use and maintenance, revealed that as many as 14% of the 594 defibrillators tested failed to meet such Association for the Advancement of Medical Instrumentation (AAMI) performance criteria as the ability to deliver energy to within 15% of the selected value and the ability of batteries to maintain the charged state over time.

Also, many of the facilities surveyed kept defibrillators in service beyond their expected useful life (5 to 8 years) — 21% of the units had been in use for more than 10 years. Under such circumstances of use, component deterioration is likely.

Scheduled preventive maintenance is another area of concern according to the survey; 20% of the 594 defibrillators in the survey were not maintained on a scheduled basis. In small hospitals and emergency departments, the devices are often maintained by the users, who lack the special training and equipment required for that function and who perform maintenance only on an as-needed basis.

charged defibrillator from remaining charged indefinitely, thereby guarding against accidental electrical shock and prolonging the life of the storage capacitors. The AAMI standard available from ECRI allows a defibrillator to remain charged for 30 to 120 seconds. (A waiver can be obtained for specific applications.) Some clinical users find the automatic disarm feature confusing; users are sometimes unsure whether the unit has functioned properly and discharged energy to the patient during a resuscitation attempt, especially those rare patients where there is the absence of distinct muscle stimulation and a "jump."

To avoid confusion, documentation on the recorder should indicate that the defibrillator was discharged and whether that discharge was to the patient through the paddles or to the internal (test) load. Also, if an incident requires investigation, a documented record of the discharge and whether it was internal or external is helpful in identifying possible causes.

Battery Failures. The maintenance of batteries — especially the nickel-cadmium type, which power many of the currently available defibrillators — is often neglected. This oversight can lead to battery failure, resulting in defibrillator failure and an inability to treat the victim of cardiac arrest.

Although the currently available batteries may be less than ideal, until a satisfactory alternative is available, battery maintenance must be vigilantly

performed to ensure the availability of adequate power during a cardiac arrest.

Varying Requirements for Training and Certification. As the CDRH survey noted, there is an absence of national standards for initial training and continuing education for defibrillator operators. The American Heart Association's ACLS certification should be mandatory for all clinicians in critical care areas of the hospital. The ACLS program describes the management of "sudden death" and cardiac emergencies through treatment protocols; in addition, it gives the ACLS provider some background material to support the rationale put forth in the protocols.

Defibrillation training should include special emphasis on operator use and safety practices, as well as defibrillator maintenance.

Finally, continuing education and skills testing should be instituted to maintain a level of competence in defibrillation procedures, as well as a familiarity with the specific defibrillator that the clinician is expected to use in an emergency. A debriefing or review can be instituted after a cardiac arrest; during this debriefing, the patient strips are reviewed to identify existing or potential problems. But hands-on skills testing and continuing education should also be implemented to aid in preventing user error or confusion.

The training of defibrillator users continues to be a problem, in part because there are no national standards for initial training and continuing education. The survey showed that 26% of the sites had no continuing education requirement, and only 16% conducted continuing education courses more than once a year.¹

Battery problems accounted for 25% of the 676 defibrillator failures reported in the CDRH survey. The maintenance of batteries — especially nickel-cadmium batteries, which power many of the currently available defibrillators — is often neglected; this neglect can lead to battery failure and an inability to defibrillate.

The survey also indicated that most batteries were used beyond their estimated useful life. Only 8% of survey responders followed the periodic maintenance procedures recommended by battery manufacturers.

Recommendations of the Defibrillator Working Group

Based on both its review of FDA and ECRI data and the five-state defibrillator survey, the Defibrillator Working

Group has established recommendations for defibrillator care and maintenance and for operator preparedness.

Recommendations for Care and Maintenance

Operators are responsible for maintaining defibrillators through daily operational checks (Appendixes A and B), careful preventive maintenance (see Appendix C), and complete reporting of problems to clinical engineering or other service personnel. The Defibrillator Working Group recommends that the checklists presented in Appendixes A and B be followed at the start of every shift. For more guidelines regarding internal paddles, see the box on page 3. The items listed for periodic care and maintenance (Appendix C) will usually be handled by clinical engineering. However, the tests can be performed by the clinical users without specialized testing equipment.

Among the recommendations of the Defibrillator Working Group is confirmation of defibrillator function by setting the device to a low energy (e.g., 50 J) and then firing the external paddles into a test load provided with the unit or into a defibrillator analyzer. For infrequent

users of defibrillators or defibrillator/monitors (e.g., one resuscitation attempt every three weeks), performance of the operational discharge test will serve as a refresher on the correct operation of the unit they are expected to use in an emergency.

Recommendations for Operator Preparedness

Training and retraining advanced life-support and other clinical personnel in the proper use and care of defibrillators and defibrillator/monitors are key factors in reducing operator error. Most ERs, CCUs, and ICUs train and recertify personnel in the use of defibrillators and defibrillator/monitors through the American Heart Association's advanced cardiac life-support (ACLS) training, which requires recertification every two years.

But the Defibrillator Working Group believes that this course inadequately addresses defibrillator maintenance and that the two years between retraining sessions is too long.

The Defibrillator Working Group's recommendations on operator preparedness (see Appendix D) emphasize initial training with hands-on, practical experience. The group also recommends instruction in proper safety procedures and periodic maintenance, as well as skill drills at least every three months. As the table notes, performance of the shift checklists is an important aspect of continuing education. This is particularly true for those clinical personnel who infrequently resuscitate patients. Rotating the task of the daily checklist to all potential users in a given area should help them stay familiar with the unit they will use in an emergency.

Familiarity becomes particularly important with the more complex devices. Some newer defibrillator/monitors include features and options that provide great versatility for skilled clinicians. With this versatility, however, comes complexity that can lead to confusion conference proceedings, *First Symposium on Human Factors in Medical Devices*, are and errors.⁶ *Because relatively few healthcare professionals use a defibrillator/monitor frequently, retraining to cope with such complexity is important.* Users should take advantage of manufacturer support in such areas as in-service videos and follow-up visits from field representatives.

ACTION RECOMMENDATIONS

- Alert users of any type of defibrillator or defibrillator/monitor to this report and to the recommendations of the Defibrillator Working Group regarding the care and maintenance of defibrillator failures (see

Appendixes A through C) and operator preparedness (see Appendix D).

- Conduct a visual inspection of these units at the start of each shift and after each clinical use. Use the shift checklists as guidelines for remaining familiar with the unit you may be called on to use.
- Perform the operational discharge test by setting battery-powered defibrillators or defibrillator/monitors to a low energy setting (e.g., 50 J or that recommended by the manufacturer) to ensure that the unit is in good working order.
- Add to the operator's maintenance and testing checklist any additional tests recommended by the Defibrillator Working Group.
- To reduce the stress normally associated with making cardiac emergency responses and to reduce the likelihood of error in discharge failures in any type of defibrillator, periodically review the effectiveness of training and retraining programs in your facility. Consult the device manufacturer and the American Heart Association about audiovisual aids and/or trainers available on request by your nursing education or cardiology departments. Schedule meetings between clinical users and engineering, as needed, to identify and resolve common user errors that may be contributing to defibrillator or defibrillator/monitor failures.
- When a battery-powered defibrillator/monitor fails to discharge when needed or if it or any other type of defibrillator fails the visual inspection or the operational test, promptly report the problem to clinical engineering or other service personnel so that they can notify the hospital risk manager, the device manufacturer, and ECRI. In this way, technical advice can be obtained, and the affected unit can be returned to service as soon as possible.

Notes

1. Cummins RO, Chesmore K, White RD, et al. Defibrillator failures. Causes of problems and recommendations for improvement. *JAMA* 1990; 264(8):1019-25.
2. ECRI. Mains (AC line) power switches on battery-powered equipment. *Health Devices* 1987; 16:345.
3. ECRI. Lifepak 5 defibrillator/monitors [Hazard]. *Health Devices* 1987; 16:112-3.
4. ECRI. Defibrillation in oxygen-enriched environments. *Health Devices* 1987; 16:113-4.
5. ECRI. Misuse of "Quick-Look" defibrillator paddles. *Health Devices* 1988; 17:68.
6. ECRI. Maintenance and user errors with the Physio-Control Lifepak 8. *Health Devices* 1990; 19:59-61.
7. ECRI. Physio-Control develops mains power switch cover. *Health Devices* 1988; 17:356.
8. Safe Medical Devices Act of 1990, Public Law 101-629.

CHECKLIST

Appendix A

Manual Defibrillators: Operator's Shift Checklist

Date: _____ Shift: _____ Location: _____

Mfr/Model No.: _____ Serial No. or Facility ID No.: _____

At the beginning of each shift, inspect the unit. Indicate whether all requirements have been met.
Note any corrective actions taken. Sign the form.

	Okay as found	Corrective Action/Remarks
1. Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
2. Paddles (including pediatric adapters)		
a. Clean, not pitted		
b. Release from housing easily		
c. If internal paddles are included, verify their availability in a sterile package. Periodically inspect as with external paddles.		
3. Cables/Connectors		
a. Inspect for cracks, broken wire, or damage		
b. Connectors engage securely		
4. Supplies		
* a. Two sets of pads in sealed packages, within expiration date		
b. Monitoring electrodes		
c. Alcohol wipes		
d. Hand towel		
e. Scissors		
f. Razor		
g. Spare ECG paper		
* h. Spare charged battery available		
* i. Cassette tape		
* j. Gel or other conductive medium present and stored properly		
5. Power Supply		
a. Battery-powered units		
(1) Verify fully charged battery in place		
(2) Spare charged battery available		
(3) Follow appropriate battery rotation schedule per manufacturer's recommendations		
b. AC/Battery backup units		
(1) Plugged into live outlet to maintain battery charge		
(2) Test on battery power and reconnect to line power		
6. Indicators/ECG Display		
a. Power-on display		
* b. Self-test ok		
c. Monitor display functional		
* d. "Service" message display off		
* e. Battery charging; low battery light off		
* f. Correct time displayed — set with dispatch center		
7. ECG Recorder		
a. Adequate ECG paper		
b. Recorder prints		
8. Charge/Display Cycle for Paddle or Adhesive Pad Defibrillation		
a. Disconnect AC plug — battery backup units		
b. Charge to manufacturer's recommended test energy level		
c. Charge indicators working		
d. Discharge per manufacturer's instructions		
e. Reconnect line power		
9. Pacemaker		
a. Pacer output cable intact		
b. Pacer pads present (set of two)		
c. Inspect per manufacturer's operational guidelines		
<input type="checkbox"/> Major problem(s) identified (OUT OF SERVICE)		

* Applicable only if the unit has this supply or capability

Signature: _____

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CHECKLIST

Appendix B

Automated Defibrillators: Operator's Shift Checklist

Date: _____ Shift: _____ Location: _____

Mfr/Model No.: _____ Serial No. or Facility ID No.: _____

At the beginning of each shift, inspect the unit. Indicate whether all requirements have been met.
Note any corrective action taken. Sign the form.

	Okay as found	Corrective Action/Remarks
1. Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
2. Cables/Connectors		
a. Inspect for cracks, broken wire, or damage		
* b. Connectors engage securely		
3. Supplies		
a. Two sets of pads in sealed packages, within expiration date		
b. Hand towel		
c. Scissors		
d. Razor		
* e. Alcohol wipes		
* f. Monitoring electrodes		
* g. Spare charged battery		
* h. Adequate ECG paper		
* i. Manual override module, key, or card		
* j. Cassette tape, memory module, and/or event card plus spares		
4. Power Supply		
a. Battery-powered units		
(1) Verify fully charged battery in place		
(2) Spare charged battery available		
(3) Follow appropriate battery rotation schedule per manufacturer's recommendations		
b. AC/Battery backup units		
(1) Plugged into live outlet to maintain battery charge		
(2) Test on battery power and reconnect to line power		
5. Indicators/*ECG Display		
* a. Remove cassette tape, memory module, and/or event card		
b. Power-on display		
c. Self-test ok		
* d. Monitor display functional		
* e. "Service" message display off		
* f. Battery charging; low battery light off		
g. Correct time displayed — set with dispatch center		
6. *ECG Recorder		
a. Adequate ECG paper		
b. Recorder prints		
7. Charge/Display Cycle		
* a. Disconnect AC plug — battery backup units		
b. Attach to simulator		
c. Detects, charges and delivers shock for "VF"		
d. Responds correctly to non-shockable rhythms		
* e. Manual override functional		
f. Detach from simulator		
* g. Replace cassette tape, module, and/or memory card		
8. *Pacemaker		
a. Pacer output cable intact		
b. Pacer pads present (set of two)		
c. Inspect per manufacturer's operational guidelines		
<input type="checkbox"/> Major problem(s) identified (OUT OF SERVICE)		

* Applicable only if the unit has this supply or capability

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Signature: _____

CHECKLIST

Appendix C

Recommendations for Periodic Care and Maintenance of Defibrillators within the Capabilities of Clinical Operators***Nickel-cadmium Battery Operator Maintenance Checklist**

Battery dates — label each battery for date manufactured and date placed in service. Useful life is generally two years, though periodic testing and reconditioning can extend this. Maintain traceable record for each battery.

Exercise procedure — perform a reconditioning or exercise procedure (deep discharge/charge three times) of the batteries every three months with battery support system available from the manufacturer. Ensure that discharge occurs to the depth specified by the manufacturer.

Battery capacity — check the capacity of the batteries following the exercise procedure every three months. They should have greater than 70% of their rated capacity after being run through the exercise procedures. If not, remove the battery from service.

Self-discharge test — perform a self-discharge test of the batteries every six months. They should self-discharge no more than 25% of measured capacity after one week. If it exceeds this rate, remove the battery from service.

Charge time test — measure the defibrillator charging time on battery power every three to six months. The defibrillator should charge to maximum rated energy level within 12 seconds with the battery at room temperature (20° to 25°C). If not, remove the battery from service.

Energy accuracy test — perform energy accuracy test every three to six months. Charge to 50 J then to 360 J, and discharge each time into a 50-ohm load energy meter. To pass, the battery must deliver $\pm 15\%$ of selected energy level; otherwise, remove it from service.

Sealed Lead-acid Battery Operator Maintenance Checklist

Full charging — sealed lead-acid batteries should be kept fully charged. Recharge fully as soon as possible after each use by plugging the defibrillator into a source of AC line power.

Constant charging — keep defibrillator (or battery, if separate from the defibrillator) plugged into AC line power during standby periods to provide constant battery charging.

No deep discharge cycling — avoid periodic deep discharge cycling because this may damage lead-acid batteries (unlike nickel-cadmium batteries).

Measure battery voltage — certain defibrillators incorporate circuitry and displays for the measurement of battery voltage and recommended voltage ranges. If such is the case, a monthly check of battery voltage is recommended.

Avoid uncharged batteries — a battery left uncharged for excessive periods (four to six months) may be damaged and require replacement. Certain defibrillators are capable of testing for damage and required battery replacement.

Battery age — check the date code on the battery. With proper maintenance and depending on use, battery life should exceed two years and may exceed five years.

* These are generic periodic maintenance recommendations that should be performed by the persons responsible for long-term periodic maintenance. While these checks will usually be performed by clinical engineers, they are within the capabilities of most clinical operators, without highly specialized testing equipment. They note the general areas that must be checked on a regular basis. Users should consult clinical engineering or manufacturers' service manuals for specific and complete details. Whenever replacement batteries are not immediately available, mark the defective unit and notify clinical engineering.

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CHECKLIST

Appendix D

**Recommendations for Operator Preparedness:
Initial Training and Continuing Education****Operators of Manual Defibrillators**

Attend a full Advanced Cardiac Life Support course, or receive at least the electrical therapy portion of the course.

Receive initial training that is specific for the device to be used clinically. This training should emphasize hands-on, practical experience.

Be instructed in proper safety procedures.

Be instructed in performance of daily maintenance checks [see Appendices A and B].

Be instructed in all periodic maintenance activities that can be performed by the operator [Appendix C].

Continuing Education for Operators of Manual and Automated Defibrillators

Performance of the daily checklist [Appendices A and B] is considered a form of continuing education; consequently, the schedules should rotate the task of the daily checklist to all potential defibrillator users in a given service area.

Practical, hands-on skill drills should be conducted at least every three months. Treatment of actual cardiac arrests counts as hands-on training; however, they should be supervised or reviewed to ensure that they are handled correctly.

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